

# PSJ3

## Exhibit 335

# APPENDIX B

## ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

### APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

### BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). See Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."
2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. See Appendix B.
3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at 14500 East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration PM0018425.
4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AIW") at McKesson Aurora.
5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration RM0220688, located at 3000 Kenskill Avenue, Washington Court House, Ohio 43160; McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration 0030849, located at 38220 Plymouth Road, Livonia, Michigan 48150; McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration PM0000771, located at 1515 Kendrick Lane, Lakeland, Florida 33805; McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration PM0020850, located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration RM0380484, located at 1955 McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration RM0173055, located at 400 Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

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distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration RM0220537, located at 3003 Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration PM0038693, located at 7009 South 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration RM0424363, located at 10504 McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration PM0021535, located at 3775 Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Delran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

## STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

### I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further



below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

- a. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers, including the following:

Aurora, Colorado;  
 Aurora, Illinois;  
 Delran, New Jersey;  
 LaCrosse, Wisconsin;  
 Lakeland, Florida;  
 Landover, Maryland;  
 La Vista, Nebraska;  
 Livonia, Michigan;  
 Methuen, Massachusetts;  
 Santa Fe Springs, California;

Washington Courthouse, Ohio; and  
West Sacramento, California.

- b. In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);
  - c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;
  - d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;
  - e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and
  - f. The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a).
4. Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

## II. Terms and Conditions

### 1. Obligations of McKesson.

- a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations.
- b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: <https://www.dea diversion.usdoj.gov/deareports/>. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).
- c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [its] area of suspicious orders," 21 C.F.R. § 1301.74(b), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day. McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: <https://www.dea diversion.usdoj.gov/deareports/>. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing.
- d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration PM0018425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or



operations involving, List I Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number PM0018425.

- e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").<sup>1</sup> This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number PM0030849. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration PM0030849, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.
- f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration RM0220688, will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (i) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section II.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number RM0220688. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

<sup>1</sup> For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II.1 e-g.

Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration RM0220688, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

- g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"). McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, 2100 North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration PM0000771, for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.
- h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, e.g., administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

- i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of \$150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances. McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.
- j. Any material breach by any McKesson facility of subsections II.1.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.
- k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.
- l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.
- m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.
- n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2. Obligations of DEA.

- a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the



negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

- b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.c. of this Agreement.
- c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.
- d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration PM0018425, and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.
- e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.
- f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration RM0220688, and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

- g. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

- a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and
- b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

- a. Any potential criminal liability;
- b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
- c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a. and b.
- d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement and Release; or
- e. Any liability based upon any obligation created by or arising under this Agreement.

### III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.
2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.
4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOJ:

Drug Enforcement Administration, Diversion Control Division, 8701 Morrisette Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrisette Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, 145 N St. NE (2 Constitution Square), 2<sup>nd</sup> Floor, East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance  
McKesson Corporation  
One Post Street, 36<sup>th</sup> Floor  
San Francisco, CA 94104

with copies to:

Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance  
McKesson Corporation  
6535 State Highway 161  
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical  
McKesson Corporation  
One Post Street, 36<sup>th</sup> Floor  
San Francisco, CA 94104

7. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8. Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of



Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

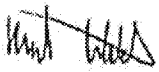
10. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

[Signature page to follow]

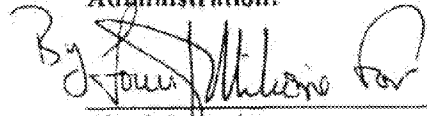
IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.


On Behalf of McKesson Corporation:

  
\_\_\_\_\_  
Mark Walchirk  
President, US Pharmaceutical  
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department  
of Justice, Drug Enforcement  
Administration:

By   
\_\_\_\_\_  
Chuck Rosenberg  
Acting Administrator  
Drug Enforcement Administration

Dated: ~~1-17-17~~  
  
\_\_\_\_\_  
Louis J. Millone  
Assistant Administrator, Diversion Control  
Division  
Drug Enforcement Administration

Dated: 1-17-17



# APPENDIX A

Appendix A  
McKesson US Pharma DCs



# APPENDIX B

**SETTLEMENT AND RELEASE AGREEMENT  
AND  
ADMINISTRATIVE MEMORANDUM OF AGREEMENT**

This Settlement and Release Agreement and Administrative Memorandum of Agreement ("Agreement") is entered into on this 2<sup>nd</sup> day of May 2008, by and between the United States Department of Justice, Drug Enforcement Administration (hereinafter "DEA") and McKesson Corporation including facilities doing business as McKesson Pharmaceutical and McKesson Drug Company (hereinafter "McKesson") (each a "Party" and collectively the "Parties").

**APPLICABILITY**

This Agreement shall be applicable to McKesson and all McKesson DEA registered facilities as identified in Appendix A.

**BACKGROUND**

WHEREAS, on August 4, 2006, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued an Order to Show Cause ("Order #1") to McKesson, with respect to its Lakeland distribution center located at 1515 West Bella Vista Street, Lakeland, Florida 33805 (the "Lakeland Facility"); and

WHEREAS, Order #1 alleged, among other things, that McKesson failed to maintain effective controls at the Lakeland Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, after service of Order #1 on McKesson, representatives of DEA and McKesson entered into discussions on how best to resolve the issues raised in the Order; and

WHEREAS, on November 1, 2007, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued a second Order to Show Cause to McKesson ("Order #2," and "Orders" when jointly referring to Order #1 and Order #2), with respect to its Landover distribution center located at 7721 Polk Street, Landover, Maryland, 20785 (the "Landover Facility"); and

WHEREAS, Order #2 alleged, among other things, that McKesson failed to maintain effective controls at the Landover Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson failed to maintain effective controls at its Conroe, Texas distribution center (the "Conroe Facility") against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson failed to maintain effective controls at its Denver, Colorado distribution center (the "Denver Facility") against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson has failed to report suspicious orders of controlled substances and to report thefts or significant losses of controlled substances as more fully set forth in Appendix B, Paragraph 8 as required by 21 C.F.R. 1301.74(b); and

WHEREAS, McKesson is registered with DEA at 39 facilities as distributors of Schedule II-V controlled substances under the provisions of the Comprehensive Drug Abuse Prevention Control Act of 1970, Title 21 U.S.C. § 801 et seq. ("CSA" or "the Act"); and

WHEREAS, McKesson denies the allegations set forth in the Orders and as otherwise summarized above and also denies any allegations of improper conduct including but not limited to allegations that it failed to maintain effective controls against diversion or failed to file suspicious order reports; and

WHEREAS, the Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest, including but not limited to sharing of information related to the distribution of controlled substances; and

WHEREAS, the Parties believe that a settlement in this matter is in the public interest and desire to settle and resolve all outstanding claims and/or issues with respect to the Orders and allegations.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, and intending to be legally bound hereby, the Parties hereto agree as follows:

#### I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, the Parties agree to resolve this matter according to the Terms and Conditions below.

2. No Admission or Concession. This Agreement is neither an admission by McKesson of liability or of any allegations made by DEA in the Orders and investigations, nor a concession by DEA that its allegations in the Orders and investigations are not well-founded.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

- (i) the conduct alleged in the Orders;

- (ii) the alleged failure of McKesson to maintain adequate controls against the diversion of controlled substances, on or prior to December 31, 2007, at all distribution facilities operated, owned, or controlled by it;
- (iii) the conduct described in Appendix B, Paragraph 8 to this Agreement; and
- (iv) the alleged failure of McKesson to detect and report suspicious orders of the controlled substances as required by 21 C.F.R. § 1301.74(b) on or before December 31, 2007.

4. DEA Headquarters. For purposes of this Agreement, the DEA Representative shall be the Chief, Pharmaceutical Investigations Section, Operations Division, DEA Headquarters.

5. McKesson Representative. For purposes of this Agreement, the McKesson Representative shall be the Senior Vice President, Distribution Operations or the Vice President, Regulatory Affairs.

## II. Terms and Conditions

### 1. Obligations of McKesson.

(a) McKesson agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a McKesson employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should be not filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1(c). This compliance program shall apply to all current and future McKesson distribution centers registered with the DEA in the United States and its territories and possessions. McKesson acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

(b) Within five (5) business days following the date of each controlled substance transaction, McKesson shall provide DEA Headquarters with a report of all controlled substance transactions through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. This information will be based on raw sales data and will not be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled, nor does this requirement supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the data provided in this report shall be a true and correct copy of the raw transaction data at the time that the data is transmitted to the DEA and thus does not contain any adjustments or corrections that would normally be part of McKesson's reconciliation of its business records. The Parties agree that the report does not



otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5). McKesson shall begin transmitting this information no later than 120 days after the Parties have mutually agreed upon a format. The obligations contained in this paragraph shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination of the obligations contained in this paragraph.

(c) McKesson shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, McKesson shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA agrees to notify all of the DEA Field Offices within 30 days of the Effective Date of this Agreement that McKesson will no longer be required to provide suspicious order reports or any other type of reports regarding excessive purchases of controlled substances to the DEA Field Offices and that this Agreement shall supersede any DEA regulatory requirements to report suspicious orders to DEA. The obligations contained in this paragraph shall be and remain in full force and effect from the Effective Date of this Agreement, and thereafter shall remain in full force and effect unless terminated and revoked by DEA with thirty (30) days written notice.

(d) McKesson agrees to a temporary suspension of its authority to distribute drugs containing the drug codes for Schedule III hydrocodone combination products and alprazolam, that is, DEA drug codes 9805, 9806 and 2882 with respect to the DEA registrations for its Lakeland Facility and its Conroe Facility, except for sales to the accounts as listed in Appendix C. The temporary suspension shall terminate in accordance with subsection II.2(g) unless sooner terminated by the Parties in writing pursuant to the terms of this Agreement.

(e) McKesson agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to McKesson's obligations to detect and report suspicious orders in accordance with 21 C.F.R. §1301.74(b).

(f) McKesson agrees that within 120 days of the Effective Date of this Agreement it will review distributions of hydrocodone and alprazolam for the 24-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of hydrocodone and alprazolam exceeded the thresholds established in its compliance program. McKesson shall conduct an investigation and take appropriate action as required by this Agreement, DEA regulations and other procedures established under McKesson's compliance program including its Controlled Substance Monitoring Program (CSMP).

(g) McKesson's policy and procedure is to cooperate with the government in any investigation. McKesson agrees to reasonably cooperate with DEA, the United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any

pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement authorities. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party.

(h) McKesson agrees to pay civil penalties to the United States of America under 21 U.S.C. § 842(c) for violations of 21 U.S.C. § 842(a)(5) in the amount of \$13,250,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances and for failing to report thefts or significant losses of controlled substances. Payment of said civil penalties shall be made by McKesson in the amounts indicated and as directed by the United States Attorneys' Offices set forth in Appendix B, Paragraph 13. McKesson agrees to execute the Settlement Agreement at Appendix B simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said civil penalties within 30 days of the Effective Date of this Agreement.

(i) Any material breach by any McKesson facility of subsections II.1(a)-(h) of this Agreement by McKesson after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of McKesson's DEA certificate(s) of registration for that facility.

## 2. Obligations of DEA.

(a) At McKesson's request, DEA shall continue to provide diversion prevention and awareness training, as practicable, to retail pharmacy industry members at McKesson trade shows and through written materials. The frequency and content of such training shall be at DEA's sole discretion.

(b) DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. §1301.74(b) and described in subsection II.1(c) of this Agreement. DEA agrees that this procedure is consistent with DEA regulatory requirements and hereby waives the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Division Offices.

(c) DEA agrees and acknowledges that neither the CSA, DEA regulations, nor the terms of this Agreement establish a requirement that reporting of a suspicious order means that a customer be designated as a suspicious customer that would de facto require the suspension of all orders or sales of other controlled substances to this customer.

(d) DEA agrees that any request made by DEA or any of its employees that McKesson continue to sell controlled substances to customers for an order that McKesson has determined to be suspicious shall be made in writing to the designated McKesson Representative.

(e) Within 150 days of the Effective Date of this Agreement, but not earlier than 90 days after the Effective Date of this Agreement, DEA shall conduct reviews of the functionality of McKesson's diversion compliance program ("Compliance Reviews") at up to eight distribution centers of McKesson, consisting of the Lakeland Facility; the Landover Facility; the Conroe Facility; and five other McKesson distribution centers selected by DEA. DEA shall also review the investigatory files maintained by McKesson of the customers serviced by the distribution centers subject to the Compliance Reviews. DEA shall notify McKesson no less than 48 hours prior to commencing a Compliance Review at a distribution center. DEA shall issue a Notice of Inspection to McKesson upon commencement of a Compliance Review. During the course of a Compliance Review, if requested, McKesson shall provide DEA with information related to the sales of controlled substances, non-controlled drugs, and listed chemicals from Effective Date of Agreement, to the date of the Compliance Review by the particular distribution center being reviewed. At the conclusion of each Compliance Review, DEA shall conduct an exit interview with an appropriate McKesson representative to provide DEA's preliminary conclusions regarding the Compliance Review.

(f) The Compliance Reviews will be deemed satisfactory unless DEA determines that one or more of the facilities being inspected has (i) failed to maintain effective controls against diversion regarding the distribution of any controlled substance; (ii) failed to detect and report to DEA suspicious orders of controlled substances; or (iii) failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances. The Compliance Reviews shall be deemed "not satisfactory" if DEA provides written notice with specificity to McKesson on or before 165 days from the Effective Date of Agreement, stating that McKesson failed to meet any of the requirements in either subsections 11.2(f)(i), (ii), or (iii) of this Agreement. DEA shall not find a Compliance Review "not satisfactory" unless the failure(s) are sufficient to provide DEA with a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against one or more of the inspected facilities. In the event that DEA provides such written notice of a Compliance Review Failure(s), DEA shall meet and confer with McKesson within 48 hours regarding such a finding. DEA shall consider remedial measures that McKesson has instituted in determining whether the Compliance Reviews are satisfactory. A finding of "satisfactory" does not otherwise express DEA's approval of the compliance program implemented at any particular distribution center.

(g) Upon the completion of the Compliance Reviews and within 180 days of the Effective Date of this Agreement, DEA will restore the drug codes 9805, 9806 and 2882 to the DEA registrations for the Lakeland and Conroe Facilities. In the event that McKesson has not satisfied DEA in regard to the Compliance Reviews within 180 days of the Effective Date of this Agreement and DEA issues a Show Cause against either of the Lakeland or Conroe Facilities, McKesson agrees to a new period of suspension of the drugs codes at such facility until the matter is resolved by mutual agreement of the Parties or a final decision by the DEA Deputy Administrator. Notwithstanding, nothing in this Agreement shall prevent the Parties from agreeing to an extension or shortening of the suspension period for these drugs codes at the Lakeland and Conroe Facilities at any time during the course of this Agreement. DEA shall not be prevented from taking any action that would otherwise be available to the agency to pursue a new period of suspension of the drug codes at these facilities.



(h) DEA shall execute this Agreement only upon obtaining a fully executed copy of the Settlement Agreement at Appendix B.

(i) In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement; all actions taken by McKesson pursuant to this Agreement; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility and at other McKesson facilities.

(j) DEA represents that it has reviewed its records for investigations or inspections, initiated or conducted prior to December 31, 2007, which may allege that McKesson failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA further represents that it has reviewed reports and records submitted by McKesson to DEA on or before December 31, 2007 for indications that McKesson may have failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA has not referred and agrees to not refer any conduct (other than conduct in Appendix B, Paragraph 8) occurring before December 31, 2007, for civil penalty proceedings under to 21 U.S.C. § 842(a)(5) that would be based on the Covered Conduct, to any other agency within the Department of Justice.

3. Joint Obligations of the Parties. McKesson and DEA agree that upon the execution of this Agreement, DEA and McKesson shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against the Lakeland Facility and Landover Facility.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

- (i) Release McKesson from any administrative claims within DEA's enforcement authority for the conduct alleged in the Orders; and
- (ii) Refrain from filing any administrative claims against McKesson within DEA's enforcement authority under 21 U.S.C. §§ 823, 824 and 842, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of December 31, 2007, and the review of the reports and records McKesson submitted to DEA prior to December 31, 2007.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct in any other administrative proceedings. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement

agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other law enforcement agency and will represent that McKesson's compliance with this Agreement adequately addressed the administrative and civil allegations raised by DEA as defined in the Covered Conduct. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

(a) Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

(b) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct subject to Paragraph II.4 of this Agreement; or

(c) Any liability based upon such obligations as are created by this Agreement.

### III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.

McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) five (5) business days after the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.

6. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction. However, the Parties agree to provide each other with advance notice the day before or as soon as possible once a decision has been made to issue any public statement or press release related to this Agreement. The Parties shall provide copies of any press release no later than two hours before issuing the press release. This paragraph does not apply to any press release or public statement issued by the Department of Justice or any United States Attorney's Office. This paragraph shall remain in effect for sixty (60) days, commencing with the Effective Date of the Agreement.

7. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

8. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

9. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties under subsections II(2)(a-d) of this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the McKesson distribution facility(s) at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.



IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

**MCKESSON CORPORATION**

By: 

John F. Hammergren  
President  
McKesson Corporation

Dated: April 28, 2008

By: 

Donald G. Walker  
Senior Vice President  
McKesson Corporation

Dated: April 30, 2008

**THE UNITED STATES DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION**

By: 

Michele M. Leonhart  
Acting Administrator  
Drug Enforcement Administration

Dated: May 2, 2008

By: 

Wendy H. Goggin  
Chief Counsel  
Drug Enforcement Administration

Dated: May 1, 2008

## Appendix A

## McKesson Distribution Center DEA Registered Facilities

<u>Location</u>	<u>DEA Registration #</u>
Carol Stream, IL	RM0220599
Methuen, MA	PM0020850
West Seneca, NY	PM0003094
Everett, WA	PM0150538
Anchorage, AK	RM0227430
Aurora, CO	PM0018425
Livonia, MI	PM0030849
Honolulu, HI	PM0001014
Santa Fe Springs, CA	PF0000012
Duluth, GA	PR0040357
Memphis, TN	PM0001951
Washington Ct. House, OH	RM0220688
Oklahoma City, OK	RM0138328
La Vista, NE	PM0038693
Tolleson, AZ	PM0021131
Wilsonville, OR	PM0022929
La Crosse, WI	RM0220537
Delran, NJ	RM0173055
Salt Lake City, UT	PM0023046
West Sacramento, CA	PM0021535
O'Fallon, MO	PM0037374
Memphis, TN	RM0207286
Lakeland, FL	PM0000771
New Castle, PA	RM0258601
Landover, MD	PD0029567
Aberdeen, SD	RM0335869
Conroe, TX	RM0328408
McCalla, AL	RM0336950
Little Canada, MN	PM0036334
Cape Girardeau, MO	RM0337534
Rocky Hill, CT	PR0104593
Aurora, CO	RM0354958

Appendix B

**SETTLEMENT AGREEMENT**

This Settlement Agreement ("Agreement") is entered into this 30<sup>th</sup> day of April, 2008, by and between the United States Department of Justice, through the United States Attorney's Offices for the Districts of Maryland, Middle Florida, Southern Texas, Colorado, Utah and Eastern California ("United States") and McKesson Corporation including facilities doing business as McKesson Pharmaceuticals and McKesson Drug Company, ("McKesson") and collectively referred to as "the Parties."

**RECITALS**

1. McKesson is a Delaware corporation and is headquartered in San Francisco, California. Among other things, McKesson is in the business of distributing branded and generic prescription drugs, as well as over-the-counter medications, to retail pharmacies throughout the United States. In furtherance of this business objective, McKesson operates numerous distribution facilities in the United States, including six facilities more fully described in Attachment A to this Agreement ("the Six Facilities").
2. As more fully described in Attachment A, McKesson holds Certificates of Registration issued by the Drug Enforcement Administration ("DEA") authorizing it to distribute controlled substances from these facilities including the Six Facilities.
3. McKesson is required to operate the Six Facilities in accordance with the statutory and regulatory provisions of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("the CSA").
4. Each of the Six Facilities supplies prescription medications, including controlled substances, to retail pharmacies and other health care providers within the respective

jurisdictions as stated in Paragraph 8.

5. DEA is the Department of Justice component agency primarily responsible for administering the CSA and is vested with the responsibility of investigating CSA violations.

6. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA in the Districts noted above. See 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

7. Methadone, Hydrocodone, Phentermine, Fentanyl and Oxycodone are medications whose manufacture, distribution, sale and possession are regulated by DEA under the CSA. This includes a requirement to report customer orders for controlled substances that are suspicious as the term is defined under 21 C.F.R. §1301.74(b).

8. The "Covered Conduct" shall mean the following alleged conduct:

A. Within the District of Maryland: From January 2005 through October 2006, McKesson-Landover sold approximately 3 million dosage units of hydrocodone to NewCare Pharmacy in Baltimore, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). Further, from August 2006 to February 2007, McKesson-Landover sold large quantities of phentermine based products to Smeeta Pharmacy in Highland, Maryland and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

B. Within the Middle District of Florida: In October 2005, McKesson-Lakeland sold approximately 2.1 million dosage units of hydrocodone to seven pharmacies in the Tampa area (Trelles Pharmacy, BiWise Drugs, Universal RX, United Prescription Service, Accumed Rx Medipharma RX and Avee Pharmacy) and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

C. Within the Southern District of Texas: From February to September 2007, McKesson-Conroe sold approximately 2.6 million dosage units of hydrocodone to Mercury Drive Pharmacy and Maswoswe's Alternative Pharmacy and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

D. Within the District of Colorado: From September 2005 through November 2007, McKesson-Aurora sold large quantities of hydrocodone to three Colorado pharmacies (Brighton Pharmacy in Brighton, Colorado; Western States Pharmacy in Brighton, Colorado; and St. Vrain's Pharmacy in Lyons, Colorado), and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

E. Within the District of Utah: From January 2005 through October 2007, McKesson-Salt Lake City sold approximately 824,000 dosage units of hydrocodone, Oxycodone, Fentanyl and Methadone to the Blackfeet Clinic in Browning, Montana, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

F. Within the Eastern District of California: From October 2007 through June 2007, McKesson-West Sacramento suffered the theft or significant loss of controlled substances on twenty-eight separate occasions, and failed to timely submit required theft and loss reports to DEA, in violation of 21 C.F.R. §§ 1301.74(c) and 1301.76(b), and 21 U.S.C. § 842(a)(5).

9. By entering into this Agreement, McKesson does not admit to the violations alleged as a result of any DEA investigation, or to any violation of law, liability, fault, misconduct, or wrongdoing. McKesson explicitly denies any allegations of violations of the CSA or DEA regulations and represents that the company has defenses to the violations alleged by the government.

10. At all times relevant to the activity alleged in these Recitals and Attachments, the CSA (21 U.S.C. § 842(c)(1)), authorized the imposition of a civil penalty of up to \$25,000 for each violation of the Section, except that violations of § 842(a)(5) (record keeping and reporting violations) are subject to a civil penalty of up to \$10,000 for each violation.

11. To avoid the delay, expense, inconvenience and uncertainty of litigation of these claims, the Parties agree to settle, compromise, and resolve all existing or potential claims for civil penalties the United States may have against McKesson under § 842 of the CSA based on the Covered Conduct as further described in Paragraphs 13 and 14 below.



12. This Agreement is neither an admission of liability by McKesson nor a concession by the United States that its claims are not well founded. In consideration of the mutual promises, covenants, and obligations set forth in this Agreement, the Parties agree as follows:

**TERMS AND CONDITIONS**

13. McKesson shall pay to the United States the sum of Thirteen Million, Two Hundred Fifty Thousand Dollars (\$13,250,000) (the "Settlement Amount") within thirty (30) days of the effective date of this Agreement, payable as follows:

A. For Conduct Alleged to have Occurred within the District of Maryland: McKesson shall pay the sum of Two Million Dollars (\$2,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Maryland, pursuant to instructions provided by the United States.

B. For Conduct Alleged to have Occurred within the Middle District of Florida: McKesson shall pay the sum of Seven Million Four Hundred Fifty-Six Thousand Dollars (\$7,456,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Middle District of Florida, pursuant to instructions provided by the United States.

C. For Conduct Alleged to have Occurred within the Southern District of Texas: McKesson shall pay the sum of Two Million Dollars (\$2,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Southern District of Texas, pursuant to instructions provided by the United States.

D. For Conduct Alleged to have Occurred within the District of Colorado: McKesson shall pay the sum of One Million Dollars (\$1,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Colorado, pursuant to instructions provided by the United States.

E. For Conduct Alleged to have Occurred within the District of Utah: McKesson shall pay the sum of Five Hundred Forty-Four Thousand Dollars (\$544,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Utah, pursuant to instructions provided by the United States.

F. For Conduct Alleged to have Occurred within the Eastern District of California: McKesson shall pay the sum of Two Hundred Fifty Thousand Dollars (\$250,000). Payment shall be by electronic funds transfer to the United States Attorney's Office,

Eastern District of California, pursuant to instructions provided by the United States.

14. In consideration of the undertakings by McKesson, the United States agrees to settle and relinquish all claims for civil penalties it may have under 21 U.S.C. § 842(c)(1) against McKesson, its officers, directors, and employees for possible violations of the CSA, and the regulations promulgated thereunder, based on the Covered Conduct.

15. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which it has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the investigation, prosecution and settlement of this matter.

16. Notwithstanding any term of this Agreement, specifically reserved and excluded from its scope and terms as to any entity or person are the following:

- A. Any potential criminal liability;
- B. Any criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Service);
- C. Any administrative liability, including mandatory exclusion from any federal programs;
- D. Any liability to the United States for any conduct other than that covered by the release in Paragraph 14; and
- E. Any claims based on such obligations as are created by this agreement.

17. McKesson acknowledges that each of its DEA registered facilities is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken good-faith actions to detect and prevent

diversion including agreeing to implement the policies and procedures that are the subject of an administrative settlement agreement between it and DEA dated May 2, 2008.

18. McKesson agrees that any and all costs it has or will incur in connection with this matter--including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, and remedial action--shall be unallowable costs for government contract accounting and for Medicare, Medicaid, TriCare, and FEHBP reimbursement purposes.

19. This Agreement is not intended by the Parties to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

20. This Agreement shall be governed by the laws of the United States. If a dispute arises under this Agreement between McKesson and an Office of the United States Attorney signing this Agreement, exclusive jurisdiction and venue shall lie in the federal judicial district of the Office with whom the dispute arose, and to the extent that state law applies to the dispute, the law of the State within the jurisdictional district shall apply. If a dispute arises under this Agreement between McKesson and more than one of the United States Attorney's Office signing this Agreement, exclusive jurisdiction and venue shall lie in the District of Maryland and to the extent that state law applies to the dispute, the law of Maryland shall apply.

21. The Parties agree that this Agreement does not constitute evidence or an admission by any person or entity, and shall not be construed as an admission by any person or entity, with respect to any issue of law or fact.

22. This Agreement constitutes the entire agreement between the Parties and cannot be amended except in writing and when signed by all the Parties to this Agreement.

23. McKesson acknowledges that its authorized representatives have read this Agreement and understand that as of its effective date, it will be a matter of public record.

24. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so.

25. This Agreement shall be effective on the date of signing by all the Parties. It may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement.

On Behalf of McKesson Corporation  
One Post Street  
San Francisco, California 94104

By: 

John H. Hammergren  
President

Dated: April 28, 2008

By: 

Donald G. Walker  
Senior Vice President

Dated: April 30, 2008


By: 

John A. Gilbert, Jr.  
Hyman, Phelps & McNamara, P.C.  
Counsel to McKesson Corporation

Dated: April 25, 2008

On Behalf of the United States

ROD J. ROSENSTEIN  
United States Attorney  
District of Maryland


By: 

Michael A. DiPietro  
Assistant United States Attorney

Dated: April 21, 2008

Dated: April 21, 2008

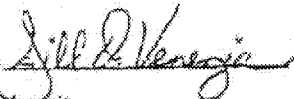
ROBERT E. O'NEILL  
United States Attorney  
Middle District of Florida

By: 

Javier Guzman  
Assistant United States Attorney

Dated: April 21, 2008

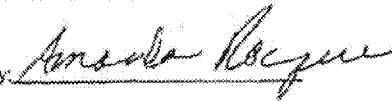
DONALD J. DeGABRIELLE  
United States Attorney  
Southern District of Texas

By: 

Jill Venezia  
Assistant United States Attorney

Dated: April 22, 2008

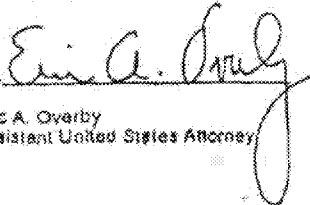
TROY A. EID  
United States Attorney  
District of Colorado

By: 

Amanda Rocque  
Assistant United States Attorney

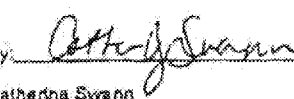
Dated: April 29, 2008

BRETT L. TOLMAN  
United States Attorney  
District of Utah

By: 

Eric A. Overby  
Assistant United States Attorney

MCGREGOR W. SCOTT  
United States Attorney  
Eastern District of California

By: 

Catherine Swann  
Assistant United States Attorney

Dated: April 29, 2008



## ATTACHMENT A

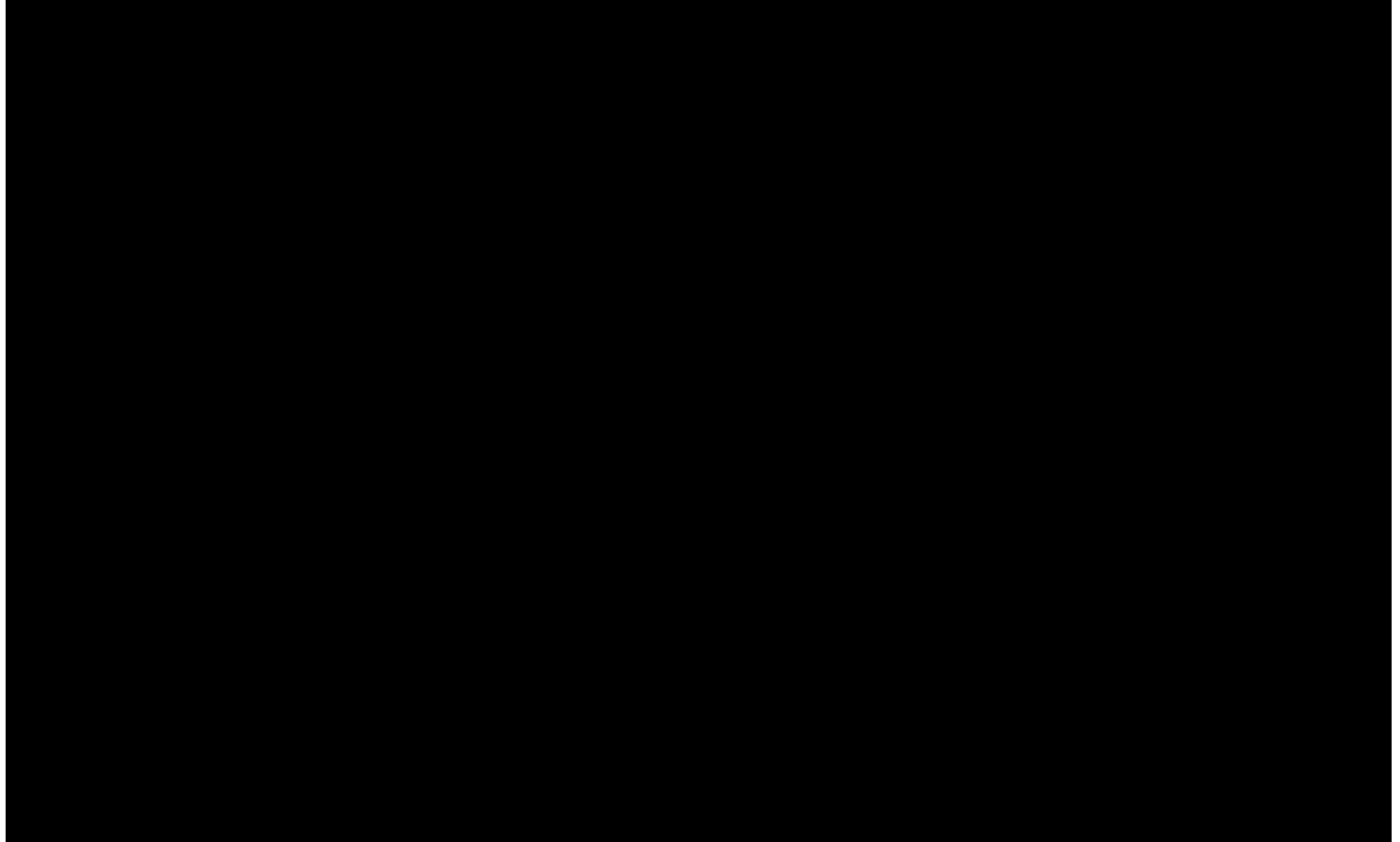
### (Six McKesson Facilities Referenced in Paragraph 1 of this Agreement)

1. 7721 Polk Street in Landover Maryland ("McKesson-Landover"), located within the District of Maryland and operating under DEA registration number PD0029567;
2. 1515 West Bella Vista Street in Lakeland Florida ("McKesson-Lakeland"), located within the Middle District of Florida and operating under DEA registration number PM 0000771;
3. 3301 Pollock Drive in Conroe Texas ("McKesson-Conroe"), located within the Southern District of Texas and operating under DEA registration number RM 0328408;
4. 14500 East 39<sup>th</sup> Avenue in Aurora Colorado ("McKesson-Aurora"), located within the District of Colorado and operating under DEA registration number PM 0018425;
5. 1900 South 4490 West in Salt Lake City Utah ("McKesson-Salt Lake City"), located within District of Utah and operating under DEA registration number PM0023046; and
6. 3775 Seaport Boulevard in West Sacramento California ("McKesson-West Sacramento"), located within the Eastern District of California and operating under DEA registration number PM 0021535.

Appendix C - Sales Accounts at Lakeland and Conroe Facilities authorized by DEA as an exception to Paragraph II.1(d).



**Appendix C - Sales Accounts at Lakeland and Conroe Facilities authroized by DEA as an exception to Paragraph II.1(d).**



Appendix C - Sales Accounts at Lakeland and Conroe Facilities authorized by DEA as an exception to Paragraph II.1(d).  
(Lakeland DC Code = 195/Conroe Code = 115)

195 KV0329688 301 CHILIS DRIVE  
VA FOXTROT  
ORLANDO FL 32824



# APPENDIX C

**FILED UNDER SEAL**